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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/888,202	07/07/1997	JULIO L. PIMENTEL		1919

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EXAMINER	
UNGAR, SUSAN NMN	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 03/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/888,202	PIMENTEL, JULIO L.	
	Examiner	Art Unit	
	Susan Ungar	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *12 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1,8,14,18,31,38 and 44-51* is/are pending in the application.

4a) Of the above claim(s) *44-46 and 52-54* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1,8,14,18,31,. 38, 47-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. The Amendment filed December 12, 2005 in response to the Office Action of August 10, 2005 is acknowledged and has been entered. Previously pending claims 38, 40-43 have been cancelled, claims 1, 8, 14, 18, 31 have been amended and new claims 44-54 have been added and Claims 44-46, 52-54 have been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions. Claims 1, 8, 14, 18, 31, 47-51 are currently being examined.

2. Claims 44-46 are directed to a method of decreasing lipase activity in feed and claims 52-54 are drawn to a method of monitoring weight change in a mammal, claims which are methods which are materially distinct methods which differ at least in objectives, method steps and reagents from each other and from the originally presented claims drawn to a method of inhibiting lipase activity in a mammal.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 44-46, 52-54 are withdrawn from consideration as being directed to non-elected invention. See 37 C.F.R. § 1.142(b) and M.P.E.P. § 821.03.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. The following rejections are being maintained:

Claim Rejections - 35 USC 103

5. Claims 1, 8, 14, 18, 31 remain rejected under 35 USC 103, and newly added claims 47-51 are rejected under 35 USC 103 for the reasons previously set forth in the paper mailed August 10, 2005, Section 10, pages 5-10.

It is noted that newly added claims 47-51 are drawn to a method of controlling weight gain in mammals by limiting lipase activity comprising administering antilipase antibody wherein said quantity of anti-lipase antibody requires an increase of more than approximately 35% in food intake to increase weight of the mammals by 1 gram (claim 47), more than approximately 450% in food intake to increase weight of the mammals by 1 gram (claim 48), wherein the antilipase antibody comprises avian antilipase antibody (claim 49), wherein the antibody is orally administered (claim 50), in feed (claim 51). It is noted that the primary prior art reference, US Patent No. 4, 598,089 is specifically drawn to methods for treating or preventing obesity, that is controlling weight gain in mammals, thus, it would have been *prima facie* obvious to one of ordinary skill in the art, and one would have had a reasonable expectation of success in controlling weight with the method of the combined references because the combined references teach both the means and motivation for inhibiting pancreatic lipase to prevent the absorption of fat in mammals which is a process that would be expected to result in controlling weight gain

The prior art references teach as set forth previously, but do not teach a method wherein said quantity of anti-lipase antibody requires an increase of more than approximately 35% in food intake to increase weight of the mammals by 1 gram, more than approximately 450% in food intake to increase weight of the mammals by 1 gram.

However, although the combined references do not teach that the quantity of anti-lipase antibody requires an increase of more than approximately 35% in food intake to increase weight of the mammals by 1 gram or more than approximately 450% in food intake to increase weight of the mammals by 1 gram, the claimed

method appears to be the same as the method of the combined references, absent a showing of unobvious differences. The office does not have the facilities for examining and comparing applicant's method with the method of the combined references in order to establish that the method of the combined prior art does not possess the same material structural and functional characteristics of the claimed method. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed methods are different than those taught by the combined prior art and to establish patentable differences. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

Applicant argues that US Patent Nos 5, 585,098 and 5,080,895 (a) are not analogous art since both patents read on treatment of diseases by administration of antibodies, (b) teach away from use to treat obesity since most diseases tend to cause weight loss and such weight loss further complicates recovery and because weight loss is an undesirable characteristic in the treatment of illness, the references would not lead one to experiment with reduction of weight and/or prevention of weight gain via antibodies, (c) there is no indication in either reference to weight or obesity that lipase activity is decreased by addition of anti-lipase antibodies.. The argument has been considered but has not been found persuasive because (a), (b) and (c). Applicant is arguing the references individually without clearly addressing the combined teachings. It must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references which made up the state of the art with regard to the claimed invention. In re Young, 403 F.2d 754, 159 USPQ 725 (CCPA 1968); In re Keller 642 F.2d

413,208 USPQ 871 (CCPA 1981). US Patent Nos 5, 585,098 and 5,080,895 are specifically cited because they teach the successful oral administration of avian antibodies, wherein the avian antibodies retain activity in the gastrointestinal tract because of their stability and because of their great resistance to acid and heat. Applicants claimed invention fails to patentably distinguish over the state of the are represented by US Patent Nos 5, 585,098 and 5,080,895 in combination with the other cited references.

Applicant argues that JP02150294 appears to state inter alia that the monoclonal antibody never inhibits the enzymatic activity of the lipase and thus teaches away from Applicant's invention. The argument has been considered but has not been found persuasive because it appears that Applicant is mischaracterizing the teaching of JP02150294. The reference states that the antibody never completely inhibits, that is partially inhibits lipase activity. It is suggested that Applicant review page 6 of the prior action wherein JP 02140294 also teaches that monoclonal antibody against pancreatic lipase hinders lipase activity. Once again, Applicant is arguing the references individually without clearly addressing the combined teachings. It must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references which made up the state of the art with regard to the claimed invention. In re Young, 403 F.2d 754, 159 USPQ 725 (CCPA 1968); In re Keller 642 F.2d 413,208 USPQ 871 (CCPA 1981).

Applicant's arguments have not been found persuasive and the rejection is maintained.

New Grounds of Rejection

Claim Rejections - 35 USC 112

6. Claims 1, 8, 14, 47-49 are rejected under 35 USC 112, first paragraph, as the specification does not contain a written description of the claimed invention. The limitation of a method for inhibiting lipase activity in a mammal comprising administering to the mammal an avian antibody in the absence of the modifying statement "orally" has no clear support in the specification and the claims as originally filed. It is noted that Applicant does not point to support in the specification for the broadening of the claims. A review of the specification reveals that the present invention relates to a method for decreasing fat absorption by orally feeding chicken antibodies against lipase (p. 4, lines 6-9), reveals "feeding anti-lipase antibodies to mice (p. 4, line 15), reveals that antibody extract can be fed in water suspension and included in feed as dry powder and/or encapsulated in liposomes (p. 4, lines 17-19), mixing the antibody with water for feeding to mice (p. 6, Example 5), reveals the feeding of anti-lipase in (Example 6, p. 10), reveals mixing the anti-lipase with the rat diet, (p. 11, line 2), feeding the antibody at Example 9, p. 12). However, in no instance is there a reference to a generalized administration of the antibody in absence of the proviso of oral administration. The subject matter claimed in claims 1, 8, 14, 18, 31, 47-49 broadens the scope of the invention as originally disclosed in the specification.

7. Claims 47-51 are rejected under 35 USC 112, first paragraph, as the specification does not contain a written description of the claimed invention. The limitation of a method for controlling weight gain in mammals by limiting lipase activity wherein an increase of more than approximately 35 % in food intake is required to increase weight of the mammals by 1 gram has no clear support in the specification and the claims as originally filed. Applicant points to support for the

newly added limitation in the claims at Example 5, page 9 of the specification. A review of the specification at page 9 reveals support for the reduced weight gain in mice fed anti-lipase antibody, wherein the anti-lipase group ingested 32.87% more feed to gain 1 gram of body weight than the control group. Nowhere in the cited support is there support for the broadly claimed mammals, nowhere in the cited support is there support for increase of more than approximately 35% in food intake required to increase weight of the mammals by 1 gram. The subject matter claimed in claims 47-51 broadens the scope of the invention as originally disclosed in the specification.

8. Claim 48 is rejected under 35 USC 112, first paragraph, as the specification does not contain a written description of the claimed invention. The limitation of a method for controlling weight gain in mammals by limiting lipase activity wherein an increase of more than approximately 450% in food intake is required to increase weight of the mammals by 1 gram has no clear support in the specification and the claims as originally filed. Applicant points to support for the newly added limitation in the specification at pages 9-10. A review of the specification at page 9 reveals as set forth above but does not reveal support for an increase of more than approximately 450% in food intake is required to increase weight of the mammals by 1 gram. A review of page 10 reveals support for 197.13 grams of feed required for anti-lipase antibody mice to gain 1 gram of body weight wherein control required only 35.70 grams of feed to gain 1 gram of body weight, wherein 451% increase in food intake, over the control mice, was required for the anti-lipase mice to gain 1 gram of body weight. Nowhere in the cited support is there support for the broadly claimed mammals, nowhere in the cited support is there support for increase of more than approximately 450% increase, over control, in food intake.

The subject matter claimed in claim 48 broadens the scope of the invention as originally disclosed in the specification.

9. Claims 18 and 31 are rejected under 35 USC 112, second paragraph because there is no antecedent basis for the term "fed" in claim 1 from which they depend.

10. Claims 47-51 are rejected under 35 USC 112, second paragraph because claims 47 and 48 are drawn to a quantity of antilipase antibody wherein said quantity of antilipase antibody requires an increase of more than approximately 35%/450% in food intake to increase weight of the mammals by 1 gram. The claims are confusing because it is not clear how the antibody can require the increased food intake.

11. All other objections and rejections recited in the previous Action are hereby withdrawn.

12. No claims allowed.

13. This action is a **final rejection** and is intended to close the prosecution of this application. Applicant's reply under 37 CFR 1.113 to this action is limited either to an appeal to the Board of Patent Appeals and Interferences or to an amendment complying with the requirements set forth below.

If applicant should desire to appeal any rejection made by the examiner, a Notice of Appeal must be filed within the period for reply identifying the rejected claim or claims appealed. The Notice of Appeal must be accompanied by the required appeal fee.

If applicant should desire to file an amendment, entry of a proposed amendment after final rejection cannot be made as a matter of right unless it merely cancels claims or complies with a formal requirement made earlier. Amendments touching the merits of the application which otherwise might not be

proper may be admitted upon a showing a good and sufficient reasons why they are necessary and why they were not presented earlier.

A reply under 37 CFR 1.113 to a final rejection must include the appeal from, or cancellation of, each rejected claim. The filing of an amendment after final rejection, whether or not it is entered, does not stop the running of the statutory period for reply to the final rejection unless the examiner holds the claims to be in condition for allowance. Accordingly, if a Notice of Appeal has not been filed properly within the period for reply, or any extension of this period obtained under either 37 CFR 1.136(a) or (b), the application will become abandoned.

14. Applicant's reference to Bookman et al prompted the new grounds of rejection and Applicant's amendment necessitated the new grounds of rejection. Thus, **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at 571-272-0787. The fax phone number for this Art Unit is (571) 273-8300.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar
Primary Patent Examiner
March 6, 2006